

Human Research Ethics Committee

Guidance notes for gaining informed consent in research with children

1. Guidance on adapting the HREC participant information sheet template for research with children

Similarly to research with adult participants, the child participant consent form should be accompanied by a participant information sheet, displaying the current Open University logo and full contact details of the PI / researcher as well as an alternative contact not directly involved in the research. This is important, so participants have an impartial contact if they have any concerns about the way the research project is being conducted.

The present guidance notes offer advice on how the generic adult research participant information sheet can be adapted to be suitable for use with child research participants. The accompanying guidance 'How to assure valid agreement by children to participate in research' (see Section 3 below) should be read in conjunction with these guidance notes.

Depending on the research context, it may be appropriate to also present the information sheet to the child's parent/guardian, with or without the child present – refer to the further advice offered in the *document on how to assure valid agreement by children to participate in research*. Typically, parent/guardian consent will also be appropriate.

Study title

The title should be simple and self-explanatory to a child of the relevant age group. It may be appropriate to use non-textual elements, e.g. pictures, to illustrate the information being conveyed, clearly and age-appropriately. This also applies to all other sections of the child participant information sheet.

Information on who is running the study, and the main contact person who the child can ask any question they may have about the study, should also be conveyed clearly and age-appropriately.

Invitation paragraph

This should explain that the child is being asked to take part in a research study. The same key elements need to be included as for adult participants, adapted to use age-appropriate language.

It may well be the case that child participants are pupils, and in this case it is important to carefully plan appropriate procedures and strategies to explain that they are entirely free to

choose not take part in the study, and that making this choice will not have any negative impact – refer to the section on ‘Respecting autonomy’ in the accompanying document on how to assure valid agreement by children to participate in research.

General information about the research study and collected research data

Include the key information as outlined in the adult participant information sheet, in terms that a child can easily understand, using non-textual elements as appropriate.

For young children it may be appropriate to exclude some of the information that would normally be included in an adult information sheet, for example information about funders.

What will I be asked to do if I agree to take part?

This information should be presented in an age-appropriate way, allowing ample opportunities for the child participant to ask questions.

How will the data I provide be used?

Child participants have the same rights as adults regarding ownership of their data, so equal respect should be given to their wishes regarding data management and storage. Age-appropriate ways of explaining these processes should be used in order to gain validly informed consent, covering the same general points as in adult participant research.

It may be appropriate to exclude some of the more technical details relating data storage, such as explanations of compliance with data protection regulations, but the child should be given clear information regarding what will happen to the data they provide.

Your right to withdraw from the study

The same basic information presented to adult participants should be conveyed to child participants, using age-appropriate language and presentation strategies.

How do I agree to take part?

Ask the child if they would like to take part in the study, and explain exactly how they should express their agreement, such as verbal agreement followed by a signature, or alternative (e.g. emoticon tick box), as indicated on a consent form.

Thank you

Remember to thank the child for taking time to look at the information sheet with you.

Data Protection

Depending on the age of the child, it may be appropriate to exclude this level of detailed information on data protection regulations, or include it in a more accessible, simplified presentation format.

2. Guidance on adapting the HREC consent form for research with children

The adult research participant template consent form can be used as a general guide, following the same standard format, but will need to be tailored to the literacy and comprehension levels of the children involved; for example, using non-textual elements where helpful and appropriate.

Informed Consent

Tick boxes, as used in adults consent forms, can work well for all but the youngest children. For young children, smiley and sad emoticon faces can be used as long as what they mean is explained clearly.

Age-appropriate language should be used.

Use of the information in the study

Certain items listed in the adult participant consent form template may be less appropriate for research with young children, such as requesting consent to use quotes, or explaining details of data storage processes. However, it may be appropriate to retain these for parent/guardian consent, where this is obtained.

Future use and reuse of the information by others

As with the other child consent form sections, this information should be presented in a simplified, accessible, age-appropriate manner.

Signatures

For young children emoticons (smiley or sad face) may be used in place of a signature.

3. How to assure valid agreement by children to participate in research

There is no one-size-fits-all approach to putting in place ethically sound protocols for ensuring that children participate freely and voluntarily in research with an appropriate understanding of what their participation involves. So much depends on the ages of the children and their developmental levels, as well as the specific demands of research projects. Best practice is for researchers to engage in early planning of their consent procedures and piloting where appropriate to ensure that the target population characteristics have been well understood and have informed the planning. Of equal importance is the need to be clear who else are stakeholders in the consenting process, for example, parents and teachers, to name those most frequently concerned. Already in the opening sentence above some of the key considerations for researchers have been alluded to: respecting children's autonomy and giving them enough and appropriate information to inform their choices.

Respecting autonomy

In common with best practice when working with adults, the default position should be to assume that the target children for participation will be capable of making an informed decision as to whether or not to participate, provided they are given adequate information in a form that they can understand and that they do not feel in any way coerced into consenting.

Similarly, children's rights as owners of their own data are no different to those of adults, so equal respect should be given to their views and wishes regarding data management, and data destruction where they so wish. Children are unlikely to have a good understanding of the implications of data storage and sharing, so these will need to be explained to them in accessible terms.

Ensuring that children are under no pressure to participate demands careful consideration of the power relations that almost inevitably exist between adults and children. Power is exerted by the context as well, for example the school or early years setting is one in which a degree of compliance with adult direction is required and enforced, either subtly and kindly, or more directly. Thus, seeking agreement from a child in such settings will already result in some degree of influence, even if it does not meet the fuzzy threshold beyond which coercion would be recognised.

Seeking participation agreement from a child is a social negotiation, not just a paper exercise. In recognition of this, careful preparation of consent procedures can include, for example, questions to which a child can be expected to say no, and encouraged by the person seeking consent making it clear that it is fine to say 'no' and that the child is free to say 'no' also to participation, and to cease participation, 'withdraw', at any time. The crucial element here is 'no consequences to saying no', and this is not always easy to convey clearly to a child.

Children are used to being in inferior power relations with adults, it is their default expectation, so a researcher will have to make special efforts to establish the different relation that establishes the child as a free agent.

With few exceptions, it is not only the child's decision regarding participation. Typically, it will be necessary to seek the consent of one or both parents or other person(s) with a legal responsibility to protect the child's best interests. If a child indicates that they do not wish to participate or that they wish to cease participation, best practice is to see the child's wishes as trumping any counter wish on the part of the parent(s) or other responsible person(s) for the child's participation to commence or continue.

For school-based research, where the research activity is identical with or very similar to standard curriculum practice, the consent of the head teacher may be sufficient in addition to child consent, as long as parents are informed of the research and it is an expectation in the school that such research may take place. The process in such cases needs to be carefully vetted by the head teacher.

Researchers should be mindful that there may be circumstances where participants will not agree to take part in the study if their parents have to be informed and give prior consent. For example in relation to sexual behaviours. In these circumstances researchers will need to satisfy the **Gillick Competency Test** (House of Lords 1985) that the young person is capable of giving informed consent.

Respecting autonomy also means being sensitive to non-verbal signs that a child is unwilling to consent or to continue participation. Signs to watch out for could include looking away, not making eye contact, becoming silent or monosyllabic in replies, withdrawing into self or nervous fidgeting.

Informing consent

The developmental age of a child, particularly in respect of literacy level as well as reasoning and decision-making capacities, is a crucial consideration when planning how best to inform the child about the research, so that their consent decision is validly informed. The information

given must be sufficiently comprehensible and clear that the child knows what they are agreeing to. Best practice is to check texts and scripts for age-appropriate literacy level and piloting with the target age group.

For younger children, the use of pictograms or other forms of graphic communication are worth considering. Similarly, the response mode to questions seeking agreement could make use of smiley or faces rather than tick boxes.

Any paper-based consenting process should normally be supplemented by a scripted introduction and a clear invitation to the child to ask any questions that they want to about what participation would entail.

Assent

While written or verbal consent is seen as the ideal form of assuring valid agreement with adults to participate in research, for children non-verbal channels are very salient in how they express their feelings. Pressures of power differential or context can induce children to agree verbally with things that they might in fact not be happy with.

Recognising that consent, or a lack of consent, can be expressed in other ways than through language leads to the important concept of assent. This requires the researcher to monitor a child's non-verbal behaviour and to be sensitive for signs that the child is not comfortable with the situation, with requests that are being made or with tasks that they are presented with. Signs of lack of assent can be many, but the most obvious are becoming withdrawn and quiet, perhaps taking longer than expected to answer questions or follow prompts, breaking and avoiding eye-contact, 'closed-in' body posture or looking towards exits or out of windows. Such signals should be seen as equally important as signatures on a consent form.

Additional resources

- The [Health Research Authority \(HRA\) website](#) has some useful examples of consent forms and information sheets used in research with children and young people.